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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/507,932

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT

PAPER NUMBER

1637

NOTIFICATION DATE

DELIVERY MODE

01/06/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/507,932	Applicant(s) ERLANDER ET AL.	
	Examiner Suryaprabha Chunduru	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Applicants' response to the office action field on July 17, 2008 has been considered and acknowledged.

Status of the application

2. Currently claims 2-38 are pending. Claim 1 is cancelled. Applicants' arguments and the amendment have been fully considered and deemed persuasive for the reasons that follow.

3. The Information Disclosure Statement filed on March 20, 2008 has been considered and acknowledged.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A. Claims 2-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al. (US 2003/0104432 A1) in view of Godfrey et al. (US 7,101,663).

Xu et al. teach a method of claim 2, 9-10, 20, 28-29, 38, for producing amplified RNA (aRNA) comprising

(a) reverse transcribing an RNA template using a promoter-primer complex and an RNA dependent DNA polymerase (reverse transcriptase enzyme) to produce a first strand cDNA (see page 5, paragraph 0073-0079, page 7, paragraph 0092)

(b) treating the reverse transcription product with RNase H enzymatic activity (see page 7, paragraph 0093);

(c) producing a second strand cDNA complementary to said first strand cDNA using a DNA dependent polymerase, in the presence of random primers to prime the synthesis of said second strand cDNA (see page 7, paragraph 0094-0095, page 9, paragraph 0119-0123);

(d) producing amplified RNA from the eluted double stranded cDNA by in vitro transcription using a DNA dependent RNA polymerase which initiates transcription from the promoter-primer complex (see page 8, paragraph 0101, page 9, paragraph 0124-01125);

wherein the product produced after c), after d) or both, is purified by contacting said product with a solid phase which binds nucleic acids followed by eluting bound nucleic acids from the solid phase dissolved in less than 50 ul (see page 9, paragraph 0125, page 11, claims 9-11, page 9, paragraph 0134).

With regard to claims 3-4, Xu et al. teach that the RNA template comprises mRNA and the template is derived from cellular mRNA preparation (see page 9, paragraph 0121).

With regard to claims 5-6, Xu et al. teach that the first primer comprises oligo d(T) comprising at least 8 dT (see page 9, paragraph 0123).

With regard to claim 7-8, 23-24, Xu et al. that the random primers are six to 10 nucleotides (see page 3, paragraph 0042, page 11, claim 17).

With regard to claims 11, 22, 25-27, Xu et al. teach that the promoter primer comprises T7 or T3 promoter sequence and second primer comprises a known sequence complementary to the 3' region of said amplified RNA (see page 7, paragraph 0092).

With regard to claims 12-19, 30-37, Xu et al. teach use of magnetic beads or silica particles to purify the first or the second cDNA product, said purification involves centrifugation at high speed without the use of a vacuum (see page 9, paragraph 0125, 0134, microcon-30 filter device).

However Xu et al. did not specifically teach completion of first and second cDNA synthesis in less than 45 minutes.

Godfrey et al. teach rapid RT-PCR method which is performed in less than 10 minutes (see col. 2, line 62-67, col. 3, line 1-3).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine a method of producing aRNA as taught by Xu et al. with a step of completing the reaction in less than 45 minutes as taught by Godfrey et al. to achieve expected advantage of developing a sensitive and enhanced method of producing aRNA. An ordinary practitioner would have been motivated to combine the teaching of Xu et al. with the step of completing the reaction in less time as taught by Godfrey et al. because one skilled in the art would have a reasonable expectation of success that the combination would result in a rapid,

automated method for RT-PCR (see col. 2, line 62-67, col. 3, line 1-3) and such modification of the method would be considered as obvious over cited prior art. Further, as noted in *In re Aller*, 105 USPQ 233 at 235, More particularly, where the general conditions (suitable volume, incubation time) of a claim are disclosed in the prior art (Xu et al. and Godfrey et al.), it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the selection of hybridization conditions performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Response to arguments:

5. With regard to the rejection of claims 2, 20-23, 25-31 under 35 USC 103(a) as being unpatentable over Baugh et al. in view of Smith et al., Applicant's arguments were fully considered and persuasive and the rejection is withdrawn herein.
6. With regard to the rejection of claims 8 and 24 under 35 USC 103(a) as being unpatentable over Baugh et al. in view of Smith et al. , further in view of Gerdes, Applicant's arguments and amendment were fully considered and the rejection is withdrawn in view of the persuasive arguments.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637

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